

## **TITLE 16. BOARD OF PHARMACY**

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments only in writing relevant to the action proposed.

Written comments must be received by the Board of Pharmacy at its office not later than 5 p.m. on October 9, 2000.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office no later than 5 p.m. on, September 22, 2000.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposal substantially as described below or may modify the proposal if the modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this notice as the contact person. The notice also will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: The Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations pursuant to the authority vested by section 4005 of the Business and Professions Code and to interpret or make specific section 4057 of the Business and Professions Code. These changes are discussed below.

### **INFORMATIVE DIGEST/PLAIN ENGLISH POLICY STATEMENT OVERVIEW**

#### **Adopt Section 1714.5, Exempt Dangerous Drugs and Dangerous Devices**

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

Section 4057 as amended by Senate Bill 1308 (Chapter 655, Statutes of 1999) removes from statute two listings of dangerous drugs and devices that are exempt from the provisions of Pharmacy Law including storage in a pharmacy under the control of a pharmacist. Further, amended section 4057 specifies that the dangerous drugs and devices that are exempt from Pharmacy Law are listed in the board's regulations.

The objective of this proposal is to place in regulation a listing of the dangerous drugs and devices that are exempt from storage in a pharmacy provided that the drugs or devices are obtained by an entity meeting specified licensure and practice criteria.

The board is proposing to adopt section 1714.5 to list the dangerous drugs and devices that are exempt from storage in a pharmacy provided that the sale or furnishing of these drugs and devices is made to a clinic, hospital, institution, or an establishment holding a currently valid and unrevoked license or permit

under Division 2 (commencing with Section 1200) of the Health and Safety Code, or Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.

### FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None. It places in regulation provisions that were previously in statute.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None

Business Impact: The board has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

This action would establish a listing of dangerous drugs and devices that are exempt from the requirements of Pharmacy Law in the board's regulations. This action would facilitate future modification of the listing.

Impact on Jobs/New Businesses: None

The Board of Pharmacy has determined that this regulatory proposal will not affect the creation of new businesses and jobs. The board has determined that the proposal will not have a significant impact on the elimination of jobs or businesses or the expansion of businesses in California.

Cost Impact on Private Persons or Entities: None

Effect on Housing Costs: None

### PLAIN ENGLISH REQUIREMENT

The Board of Pharmacy has determined that the proposed regulations would affect small businesses. This proposal would affect only those businesses that choose to store the specified dangerous drugs and devices outside a pharmacy.

The express terms of the proposed action written in plain English are available from the agency contact person named in this notice.

### CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no alternative which it considered would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

#### STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared a statement of the reasons for the proposed actions and has available all the information upon which the proposal is based.

#### TEXT OF PROPOSAL

Copies of the exact language of the proposed regulation and of the statement of reasons and other information, if any, may be obtained at the hearing or prior to the hearing upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814.

#### CONTACT PERSON

Inquiries concerning the proposed administrative action may be addressed to Patricia Harris at the above address or at (916) 445-5014.